PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
HADASSA WATERMAN
G.E. EHRLICH (1995) LTD.
11 MENACHEM BEGIN STREET
RAMAT GAN, ISRAEL 52 521

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	01 JUL 2008
Applicant's or agent's file reference 32329	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL06/00834	19 July 2006 (19.07.2006)	19 July 2005 (19.07.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 6/00**(2006.01)
USPC: 600/436

Applicant

SPECTRUM DYNAMICS LLC

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	11 June 2008 (11.06.2008)	Ruth Smith Telephone No. 571-272-4745

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00834

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00834

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. Citations and explanations:

Please See Continuation Sheet

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448
The opinion as to Novelty was negative (No) with respect to claims NONE
The opinion as to Inventive Step was positive (Yes)with respect to claims NONE
The opinion as to Inventive Step was negative(NO) with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over DeVito et al.

DeVito et al. show a SPECT type of tomographic imaging system. The system can move in relation to the patient (column 6, lines 29-40). The system can accept user inputted commands or data to control the system (column 13, lines 35-67). The system is described for use in a heart perfusion study. The patient is given either a physical or pharmacologic stress. During stress, a radiopharmaceutical is then administered, and the patient is imaged. After a period of rest, another dose is administered and the patient is imaged again. The images of the stress period and rest period are compared. Such a technique is common and well known in the art for a myocardial perfusion study (column 24, lines 9-50). DeVito et al. further discusses imaging the brain, breast, or limbs.

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over Ryals et al.

Ryals et al. show a method and apparatus for SPECT imaging. Ryals et al. describe SPECT systems which are moved around the area to be imaged, and notes that such systems are well known in the art. Ryals et al. also describe common cardiac perfusion studies, which involve examining the heart under a stress condition and a rest condition. The radionuclide introduced to the heart will follow the blood flow, and perfusion can be determined. Infarct and ischemic areas of the heart can be identified (column 1, line 40-column 2, line 24; also column 8, line 56-column 9, line 15; column 16, line 61-column 17, line 20).

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in

Supplemental Box
In case **the space in any of the preceding boxes is not sufficient**.

any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 lack an inventive step under PCT Article 33(3) as being obvious over Bishop et al.

Bishop et al. show a cardiovascular imaging and functional analysis system. The use of such a system for myocardial perfusion studies under stress is discussed ([0077]). The use of different types of radiopharmaceuticals is discussed ([0118]-[0120], [0125]).

It would be obvious to one of ordinary skill in the art, at the time the invention was made, to have imaged other parts of the body. Techniques for imaging other parts of the body are well known in the art, and would be administered to a patient suffering a condition in any other part of the body which would require imaging to evaluate. In addition, the use of a variety of different radiopharmaceuticals could be used in such a system, so long as they allow for the patient to be imaged appropriately. Also, the specific length of times for which the patient should be rested, stressed, and imaged can be different for different patients, and a physician would be able to determine the appropriate length of time. The physician will also be able to determine the appropriate dosage to administer to the patient.

Claims 1-276, 283-289, 291, 293, 296-350, 352, 364-366, 368-370, 373-379, 383, 385-448 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.